Remarks

Claims 1-39 are pending in this application. Applicant acknowledges Claims 10-39 have been withdrawn from consideration. Claims 1 and 9 have been amended. New Claims 40-49 have been added to further define aspects of the invention. The amendments made herein to the claims do not incorporate new matter into the application as originally filed. Support for the amendments can be found in the drawings and throughout the instant specification.

As an initial matter, it should be noted that the present invention is directed to a delivery device for introducing a substance directly at least via a side-port into selected region(s) of the skin. Such systems are desirable in order to accurately place a deposit of substance within the skin as well as to reduce the delivery pressure to the skin. The side-ported device may be supplied from a removable external reservoir, such as a syringe. Additionally, it is desirable to have a system that is able to selectively deliver a substance to the skin such that there would be reduced leakage from both the skin and the device when the system is pressurized from the connection of needle to reservoir. The device of the instant application includes a needle and at least one outlet positioned perpendicular to the insertion axis of the needle. The needle has a specific length and outlet placement for directing said substance under pressure from the reservoir into the skin. As has been discovered, the threshold pressures involved with delivery to the skin are much higher than the pressures to deliver to other tissues, and therefore a system according to the present invention, capable of lowering delivery pressures, is required to deliver to the skin without adverse effects *such as* leakage from the connections to the device.

As discussed more fully below, U.S. Patent No. 6,319,230, hereinafter "Palasis," discloses a device for delivering and injecting fluid into *heart tissue* utilizing a laterally directed needle to increase fluid retention in the heart tissue. The device has two penetrating members, one of which penetrates the heart tissue at the injection site in a first direction, and a second, which penetrates the heart tissue in a second direction different from the first direction. (See Fig. 2 of Palasis.) The primary driver for the device

of Palasis is to reduce fluid leakage from the injection site and to increase the volume of treated tissue by delivering the fluid away from the needle.

Claim Rejections under 35 USC § 102

The Examiner has rejected Claims 1-9 under 35U.S.C.§102(b) as being anticipated by Palasis. Applicants respectfully traverse this rejection. Claim 1, as presently amended, now recites a needle for delivery of a substance to the skin which includes a skin engaging surface, a specific penetration length as measured from the skin engaging surface, and at least one side port with a specific location as measured from the skin engaging surface.

Palasis discloses a device for delivering and injecting fluid into heart tissue utilizing a laterally directed needle to increase fluid retention in the heart tissue. Applicants cannot find in Palasis a teaching or suggestion of selectively delivering the substance into the skin of the patient by a skin penetration member via a side-ported outlet. Furthermore, applicants cannot find in Palasis a teaching or suggestion of dimensional constraints for selectively delivering a substance into skin, or a skin engaging surface. To support a rejection of a claim under 35 U.S.C. § 102(b), it must be shown that each element of the claim is found, either expressly described or under principles of inherency, in a single prior art reference. In addition, the prior art reference must disclose the limitations of the claimed invention "without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference." Therefore, since Palasis does not describe or suggest any of these limitations, Palasis cannot anticipate the Applicants' invention as claimed.

Furthermore, the Palasis device requires secondary penetration members (26), which are directed through the needle (24) and out the aperture (34) of the device. The needle (24) of Palasis has specific structure as shown in Fig. 2 for directing secondary needle (26) out of aperture (34). It is understood from the disclosure that **substances delivered through the Palasis device exit only at the distal end (32) of the secondary penetration members (26) at least 0.500 mm from aperture (34)**. The specific

paragraphs of Palasis explaining the structure of needle conduits and apertures have been reproduced below for the Examiner's convenience.

Palasis Column 3, Lines 13-22 and Fig. 2

Any practical number of secondary penetrating members may be used, but preferably 1 to 20 secondary penetrating members are utilized. The secondary penetrating members may have a diameter in the range of approximately 27 to 40 Gauge, and a penetrating length in the range of approximately 0.5 to 5 mm. The primary penetrating member is typically larger than the secondary penetrating members with a diameter in the range of approximately 20 to 36 Gauge, and a penetrating length in the range of approximately 1 to 10 mm.

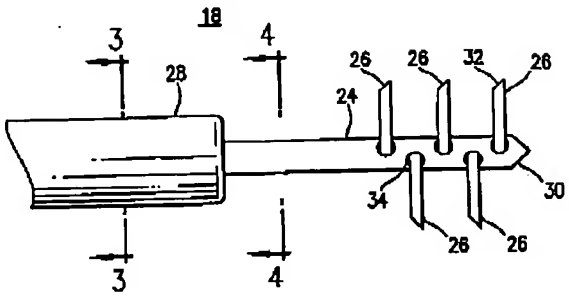

FIG.2

Palasis Column 6, Lines 47-53 and Fig. 5

The insert 40 illustrated in FIG. 5 has been simplified for purposes of illustration only by omitting the secondary penetrating member 26 and showing only one channel 42 corresponding to a single aperture 34. However, it is to be understood that a plurality of channels 42 may be provided to correspond to the number of secondary penetrating members 26 and the number of apertures 34 utilized.

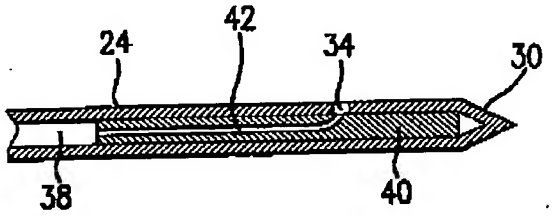

FIG.5

Aperture (34) of Palasis is not equivalent to the side port of the instant invention. In reality, the aperture (34) of Palasis is a needle aperture, not a substance aperture and consequently substances delivered through the Palisis device, by its very nature, are delivered away from the primary needle. In contrast, the Applicants' invention delivers the substance directly from the side port.

Even if the Palasis device performed all the functions recited in Claim 1, the device of Palasis cannot anticipate the claim if there is any structural difference. (See MPEP § 2114 and *In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1951 (Fed. Cir. 1999)*). Furthermore, support a rejection of a claim under 35 U.S.C. § 102(b), it must be shown that each element of the claim is found, either expressly described or under principles of inherency, in a single prior art reference. The apertures of Palisis are needle apertures not substance apertures. Thus, Applicant's submit that currently amended

Claims 1-9 are allowable over Palasis since the structure of Palasis is different from the applicant's invention.

Furthermore, the Applicants' invention structure omits key elements of Palasis, namely the secondary needles and associated guiding features, yet has a similar function to that of the Palasis device in that both deliver to tissues radial to the needle. One would not be inclined to modify the device of Palasis to deliver to tissue adjacent to the primary needle, as the thrust of the Palasis device the ability to deliver away from the primary needle.

New Claims

New claims 40-46 have been added to further define aspects of the invention, which are fully supported by the instant specification. Accordingly, no new matter has been added. New independent claim 40 has the same elements and structure as amended Claim 1 but in addition recites a side port with specific characteristics, which is placed in a specific layer of skin. For all of the reasons discussed previously, none of the references, alone or in combination, teach or suggest the use of a skin engaging surface, and specific placement of side port(s) in an intradermal delivery device having a specific penetration limiting means as outlined in Claim 40. Without discussing each in detail, it will be appreciated that the claims depending from Claim 40 recite additional features that are not taught or suggested by the prior art.

Conclusion

In view of the Remarks above, applicant respectfully submits that Claims 1-9 and 40- 49 are in condition for allowance, and respectfully requests that the Examiner earnestly reconsider the rejections of the present application. Applicant hereby authorizes the Commissioner to charge the fees necessary in connection with this Response and Extension of Time and any other fees necessary in connection with this application, to Deposit Account Number 02-1666.

In light of the above amendments and remarks, Applicant respectfully requests that the Examiner enter the amendments and consider the remarks made herein. Consideration and prompt allowance of the claims are respectfully submitted.

Any questions concerning this application or amendment may be directed to the undersigned agent of applicant.

Respectfully submitted,

By: _____

Dated: December 22, 2004.

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